

REMARKS/ARGUMENTS

The indication of allowability of claim 6 on page 7 of the office action is noted with appreciation. Claim 6 has been rewritten in independent form to include the limitations of the claims on which it depended, and is allowable.

The claims have also been amended in response to the indefiniteness rejection and are submitted to now fully comply with 35 USC 112, second paragraph.

The invention, as claimed in independent claim 1 and new independent claim 16, is directed to a multidose inhaler that includes an electrical circuit and electronic display that displays an indication of usage of the inhaler (e.g., doses used or doses remaining). The multidose inhaler includes a rotatable dosing unit and a rotatable member that is connected to the rotatable unit and has a cam that physically contacts a contact element of a switch and moves it from one position to another as the rotatable dosing unit is moved to supply a dose to an inhalation channel of the inhaler. The direct physical contact of the cam with the electrical contact provides a simple and very reliable switch activation. Claim 16 also recites that the inhaler includes a housing and that an inhalation channel member, the rotatable dosing unit, the rotatable member with the cam, and the electrical circuit are all within the housing, that the electronic display is in an opening in the housing, and that a contact element of the switch is in the path of travel of the cam so as to be displaced between a first open position and a second closed position when a dose of medicament is provided to the inhalation channel.

The claims (with the apparent exception of claim 6) were rejected under 35 USC 103(a) on the basis of Ambrosia in view of Wolf. Ambrosia was cited for disclosure of an inhaler with a rotatable dosing element, a mechanical dose counter, and rotatable member with a cam. Wolf was cited for disclosure of an electrical counter on an inhaler.

The combination of references, however, fails to disclose or suggest the type of switch and switch activation that is required by claims 1 and 16. Claim 1 recites that the cam is in physical contact with the contact element and causes movement of the contact element as a dose is delivered. Claim 16 recites that the contact element is located within the path of travel of the cam so as to be displaced between a first open position and a second closed position (i.e., open to closed or closed to open) when a dose of medicament is provided to the inhalation channel. As

A

noted above the direct physical contact of the cam with the electrical contact provides a simple and very reliable switch activation.

In the rejection, Ambrosia is said to have a “dose counting unit (580)” [presumably “590” is intended] and “a rotatable member (90) connected to the dosing unit, which is a cam (a rotating or sliding piece in a mechanical linkage) having a camming surface (Fig. 9), configured to rotate the dosing unit to provide a dose of medicament to the inhalation channel.” The claims, however, require that the cam “cause movement of the contact element” (claim 1) or “displace” the contact element (claim 16), not rotate the dosing unit.

Wolf does not make up the deficiencies of Ambrosia. Wolf describes a device that is mounted on a conventional inhaler. The device includes a sheath 120 and an electronic housing 110 that connect to the inhaler. The sheath includes magnets 122 which rotate with the sheath when a dose is being supplied. The electronic housing includes “activation sensing elements 435 and 436” (e.g., reed switches) that open or close as the “magnet 122 (embedded in the wall of activation sheath 120 of Fig. 1) comes within the proximity of the magnetic field.” (col. 6, lines 9-19).

Thus the combination of references nowhere discloses or suggests a cam on a rotatable member that rotates with the dosing unit to “physically contact” and “move” an electrical contact or “displace” a contact “within the path of travel of the cam,” as required by independent claims 1 and 16. Accordingly, independent claims 1 and 16 are patentable under 35 USC 103(a).

The remaining claims depend on independent claims 1 and 16 and are allowable for at least the reasons already mentioned.

Attached is a marked-up version of the changes being made by the current amendment.

A

Applicant : Goran Marnfeldt
Serial No. : 09/297,899
Filed : May 10, 1999
Page : 8

Attorney's Docket No.: 06275-184001

Applicant asks that all claims be allowed. Enclosed is a check for 110.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: March 7, 2001

William E. Booth
William E. Booth
Reg. No. 28,933

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

20196824.doc

A

In the claims:

Claim 1-15 has been amended as follows:

1. (Amended) An inhaler for administering medicament by inhalation, comprising:
an inhalation channel [(24)];
a rotatable dosing unit [(16)] which includes at least one dosing element [(18)] for providing a dose of medicament to the inhalation channel [(24)]; and
a dose counting unit [(42)] which comprises an electronic display [(57)] that displays usage of said inhaler, an electrical circuit for counting each dose of medicament provided to the inhalation channel [(24)] and driving the display [(57)] so as to provide an indication as to [the] said usage of the inhaler, the electrical circuit including at least one switch which comprises a contact element [and is one of opened or closed] that is movable between a first open position and a second closed position when a dose of medicament is provided to the inhalation channel [(24)], and a rotatable member [(45)] connected to the dosing unit [(16)] so as to be rotatable therewith, the rotatable member [(45)] including at least one cam surface [(51, 52)] which includes at least one cam [(51a, 52a)], each cam [(51a, 52a)] on each cam surface [(51, 52)] being configured, on rotation of the dosing unit [(16)] to provide a dose of medicament to the inhalation channel [(24)], [such as] to be in physical contact with said contact element and cause movement of the contact element of the respective at least one switch [and one of open or close the same] from one said position to another said position.

2. (Amended) The inhaler of claim 1, wherein the electrical circuit includes a first switch which comprises a first contact element and a second switch which comprises a second contact element and the rotatable member [(45)] includes first and second cam surfaces [(51, 52)] which each include at least one cam [(51a, 52a)] which is configured to cause movement of a respective one of the first and second contact elements [so as to one of open or close the first and second switches] from one said position to another said position.

A

3. (Amended) The inhaler of claim 1, wherein the dosing unit [(16)] includes a plurality of dosing elements [(18)] and each cam surface [(51, 52)] includes a plurality of cams [(51a, 52a)] having the same angular spacing as the dosing elements [(18)] in the dosing unit [(16)].

4. (Amended) The inhaler of claim 3, wherein the plurality of dosing elements [(18)] in the dosing unit [(16)] and the plurality of cams [(51a, 52a)] on each cam surface [(51, 52)] are angularly equi-spaced.

5. (Amended) The inhaler of claim 2, wherein the corresponding cams [(51a, 52a)] on the first and second cam surfaces [(51, 52)] are rotationally offset in relation to one another such that one of the first and second switches is one of opened or closed before the other.

6. (Amended) [The inhaler of claim 5] An inhaler for administering medicament by inhalation, comprising:

an inhalation channel;

a rotatable dosing unit which includes at least one dosing element for providing a dose of medicament to the inhalation channel; and

a dose counting unit which comprises an electronic display that displays usage of said inhaler, an electrical circuit for counting each dose of medicament provided to the inhalation channel and driving the display so as to provide an indication as to said usage of the inhaler, the electrical circuit including at least one switch which comprises a contact element that is movable between a first open position and a second closed position when a dose of medicament is provided to the inhalation channel, and a rotatable member connected to the dosing unit so as to be rotatable therewith, the rotatable member including at least one cam surface which includes at least one cam, each cam on each cam surface being configured, on rotation of the dosing unit to provide a dose of medicament to the inhalation channel, to cause movement of the contact element of the respective at least one switch from one said position to another said position,

wherein the electrical circuit includes a first switch which comprises a first contact element and a second switch which comprises a second contact element and the rotatable member includes first and second cam surfaces which each include at least one cam which is configured to cause movement of a respective one of the first and second contact elements from one said position to another said position,

wherein the corresponding cams on the first and second cam surfaces are rotationally offset in relation to one another such that one of the first and second switches is one of opened or closed before the other,

wherein the cams [(51a, 52a)] on the first and second cam surfaces [(51, 52)] are rotationally offset such that, on rotation of the rotatable member [(45)], in a first phase of rotation one of the first and second switches is closed and the other of the first and second switches is open, in a second phase of rotation the first and second switches are closed, in a third phase of rotation the one of the first and second switches is open and the other of the first and second switches is closed, and in a fourth phase of rotation the first and second switches are open, and the electrical circuit is configured to count only when this sequence of closing and opening the first and second switches is followed.

7. (Amended) The inhaler of claim 1, wherein each contact element is a resiliently-biased arm [(62, 63)] which includes a first part which rides on the respective cam surface [(51, 52)] and a second part which provides a contact pad [(62b, 63b)].

8. (Amended) The inhaler of claim 7, wherein the arm [(62, 63)] is resilient and configured such that the second part thereof which provides a contact pad [(62b, 63b)] moves at least partly laterally over a contact surface when the first part thereof rides onto and over a cam [(51a, 52a)].

9. (Amended) The inhaler of claim 7, wherein the arm [(62, 63)] includes a bend [(62a, 63a)], the outer surface of which rides on the respective cam surface [(51, 52)].

10. (Amended) The inhaler of claim 1, wherein the dosing unit [(16)] includes a shaft [(20)] which includes a surface provided with one of at least one of an external or internal spline [(38)] and the rotatable member [(45)] includes a surface provided with the other of at least one of an external spline [(54)], the splines [(38, 54)] being engaged such that the dosing unit [(16)] and the rotatable member [(45)] in use rotate concomitantly.

11. (Amended) The inhaler of claim 1, wherein the electrical circuit is configured to drive the display [(57)] to display the number of doses used.

12. (Amended) The inhaler of any claim 1, wherein the electrical circuit is configured to drive the display [(57)] to display the number of doses remaining.

13. (Amended) The inhaler of claim 12, wherein the electrical circuit is configured to drive the display [(57)] to display intermittently the number of doses remaining when a predetermined number of doses or less are remaining.

14. (Amended) The inhaler of claim 1, wherein the display [(57)] is a liquid crystal display.

15. (Amended) The inhaler of any of claim 1, further comprising a rotatable grip portion [(4)] which is in use gripped by a user and when rotated in one sense rotates the dosing unit [(16)] to provide a dose of medicament to the inhalation channel [(24)].

--16. An inhaler for administering medicament by inhalation, comprising:
a housing member extending along a vertical axis, said housing member having an opening;

an inhalation channel member within said housing member extending substantially parallel to said vertical axis, said inhalation channel member having an inlet, a middle portion, and an outlet portion;

a rotatable dosing unit within said housing which includes at least one dosing element for providing a dose of medicament to said inlet of said inhalation channel member; and

a dose counting unit including a rotatable member connected to the dosing unit so as to be rotatable therewith, said rotatable member having a cam and being located adjacent to said middle portion within said housing, said dose counting unit also including an electronic circuit that includes a switch with a contact element located within the path of travel of said cam so as to be displaced between a first open position and a second closed position when a dose of medicament is provided to the inhalation channel, said circuit counting doses provided to said inhalation channel, said dose counting unit including an electronic display that is aligned with said opening in said housing, is connected to said electrical circuit and displays an indication of doses supplied to said inhalation channel of said inhaler.

A



PRV
PATENT- OCH REGISTRERINGSVERKET

The enclosed Certificate of Registration has been issued for

AstraZeneca Aktiebolag
registration number: 556011-7482

which is registered as "PUBLIKT", generally written (publ), in the Companies Register kept by this office, the Companies Department of the Patent and Registration Office, Sweden.

A Swedish company classed as "PUBLIKT" is entitled to invite the general public to subscribe for or acquire shares and other securities which the company issues.

The share capital for a company classed as "PUBLIKT" must amount to a minimum of SEK 500 000.

Sundsvall, 15th February, 2000

RECEIVED
MAR 16 2001
TC 3700 MAIL ROOM

A

PRV

PATENT- OCH REGISTRERINGSVERKET
Bolagsavdelningen

Page 1

CERTIFICATE OF REGISTRATION

SWEDEN

Registration number: 556011-7482
Date of registration: 1913-10-31
Company name: AstraZeneca AB
Address:
Registered office: 151 85 SÖDERTÄLJE
Södertälje
Share capital: SEK 2.054.029.452,50
Note: FUSION IN PROGRESS



BOARD OF DIRECTORS:

440802-3556 Björnsson, Björn Einar, (A), Bäckahästvägen 3,
240 13 GENARP
420527-5938 From, Per Anders Gideon, Drottningholmsvägen 1 6tr.,
112 42 STOCKHOLM
500523-4330 Lerenius, Per Göran, (E), Pettersbergsvägen 66,
129 40 HÄGERSTEN
430319 McKillop, Thomas Fulton Wilson, (E), (O), Flat 3,
15 Stanhope Gate, LONDON W1Y 6LN, STORBRITANNIEN OCH NORDIRLAND
590228 Symonds, Jonathan, (E), 16 Moor Lane, Rickmansworth,
Hertfordshire, WD3 1LG, STORBRITANNIEN OCH NORDIRLAND
591026-0024 Sörensen, Pia Carina, (A), Skämylövsvägen 6,
640 60 ÅKERS STYCKEBRUK
560902-0093 Wallenberg, Marcus, Vidbynäs Gård 33, 148 91 ÖSMO
390324-5714 Wilhelmsson, Claes-Erik, Strandvägen 63,
115 23 STOCKHOLM

DEPUTY MEMBERS OF THE BOARD:

690810-6690 Johansson, Stig-Ove Michael, Ekhöjden Taxinge-Näsby,
155 93 NYKVARN
580928-3335 Lundblad, Karl Alf Lennart, Envigsgränden 1,
224 75 LUND

MANAGING DIRECTOR:

420527-5938 From, Per Anders Gideon, Drottningholmsvägen 1 6tr.,
112 42 STOCKHOLM

OTHER PERSONS AUTHORIZED TO SIGN ON BEHALF OF THE COMPANY:

520121-1751 Johansson, John Roland, Pilvägen 8, 610 60 TYSTBERGA
561115-2710 Johansson, Per Olof Kjell, Bränningstrandsvägen 72,
151 39 SÖDERTÄLJE
580712-5116 Linde, Carl Fredrik Johannes, Auravägen 24,
182 68 DJURSHOLM
580111-2086 Ljungqvist, Margit Inga Susanne, Solhemsvägen 13A,
141 31 HUDDINGE

True copy certified by:

CONTD.

[Signature]

A

PRV

PATENT- OCH REGISTRERINGSVERKET
Bolagsavdelningen

Page 2

CERTIFICATE OF REGISTRATION

SWEDEN

Registration number: 556011-7482
Date of registration: 1913-10-31
Company name: AstraZeneca AB
Address:
Registered office: 151 85 SÖDERTÄLJE
Södertälje
Share capital: SEK 2.054.029.452,50
Note: FUSION IN PROGRESS

470520-1939 Sveréus, Björn Gustaf, Hedåvägen 9, 152 51 SÖDERTÄLJE

COMPANY AUDITORS:

430319-0658 Magnusson, Bo Vilhelm, Karpvägen 36, 181 30 LIDINGÖ

COMPANY AUDITOR:

556479-9103 Deloitte & Touche Stockholm Aktiebolag
Box 101 52, 121 26 STOCKHOLM-GLOBEN
Principal responsible auditor: 430319-0658 Magnusson, Bo Vilhelm
Karpvägen 36, 181 30 LIDINGÖ

SIGNATORY POWER:

In addition to the Board of Directors,
Lerenius, Per Göran
McKillop, Thomas Fulton Wilson
From, Per Anders Gideon
Linde, Carl Fredrik Johannes
individually,

or

any two jointly of

Wilhelmsson, Claes-Erik
Johansson, John Roland
Johansson, Per Olof Kjell
Ljungqvist, Margit Inga Susanne
Sveréus, Björn Gustaf

are entitled to sign on behalf of the company.

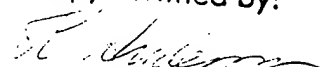
SECONDARY NAMES:

Astra

FINANCIAL YEAR:

Registered financial year: 0101-1231
Latest annual report submitted covers financial
period 980101-981231

True copy certified by:



CONTD.

A

PRV

PATENT- OCH REGISTRERINGSVERKET
Bolagsavdelningen

Page 3

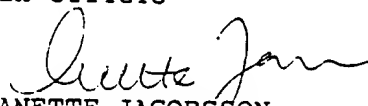
CERTIFICATE OF REGISTRATION

SWEDEN

Registration number: 556011-7482
Date of registration: 1913-10-31
Company name: AstraZeneca AB
Address:
Registered office: 151 85 SÖDERTÄLJE
Södertälje
Share capital: SEK 2.054.029.452,50
Note: FUSION IN PROGRESS

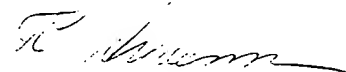
DATE OF REGISTRATION OF CURRENT AND PREVIOUS COMPANY NAMES:
2000-01-03 AstraZeneca AB
1994-06-20 Astra Aktiebolag
1966-05-12 Aktiebolaget Astra
1913-10-31 Aktiebolaget Astra, Apotekarnas Kemiska Fabriker

SUNDSVALL 2000-02-15
Ex officio

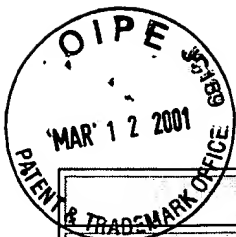

ANETTE JACOBSSON

- (A) = employee representative
- (U) = person resident outside EEA
- (E) = person resident outside Sweden but within EEA
- (O) = Chairman of the Board

True copy certified by:



A



PTO CHECK REQUEST

118545

Date Requested	11/07/2000			
Requested By	Janis K. Fraser, Ph.D., J.D./jhp			
Matter Name	D 1969-1P US			
Matter ID	06275-184001			
Payable To	Commissioner of Patents and Trademarks			
Check No.	118545			
Check Date				
Check Amount	\$40.00			
Category	Amount	Client Share	Partner Share	Office Share
801 Assignment Recordation Form Cover Sheet	\$40.00	\$40.00	\$	\$
	\$	\$	\$	\$
	\$	\$	\$	\$
1 Month <input type="checkbox"/> Small Entity-\$55 <input type="checkbox"/> Large Entity-\$110	\$	\$	\$	\$
2 Month <input type="checkbox"/> Small Entity-\$195 <input type="checkbox"/> Large Entity-\$390	\$	\$	\$	\$
3 Month <input type="checkbox"/> Small Entity-\$445 <input type="checkbox"/> Large Entity-\$890	\$	\$	\$	\$
4 Month <input type="checkbox"/> Small Entity-\$695 <input type="checkbox"/> Large Entity-\$1390	\$	\$	\$	\$
5 Month <input type="checkbox"/> Small Entity-\$945 <input type="checkbox"/> Large Entity-\$1890	\$	\$	\$	\$
Billing Attorney	Janis K. Fraser, Ph.D., J.D.			
Charge Office ¹				
Explanation				
Responsible Attorney Signature		Date		
Approval Signature ²	GRLee	Date		

RECEIVED
MAR 16 2001
TC 3700 MAIL ROOM

20172088.doc

¹ If charged to office, the remainder of the form must be completed. If an extension fee, continuation, divisional, or fwc filing fee, or notice of appeal fee is charged to the office, the responsible partner shares the cost and must sign this request. In cases of combined attorney/client delay, the partner is expected to bill a reasonable amount to the client. Any remaining amount will be divided between the partner and the office according to the applicable percentage (0% of month 1 fee + 25% of month 2 fee + 50% of month 3 fee + 50% of month 4 fee).

² All client-related office charges greater than \$200 must be approved by GRLee. If advance approval is not possible, the person requesting the check must submit a write off request to GRLee as soon as possible. Forms are found in Public Folders..

A